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III. REMARKS

Applicants respectfully request reconsideration of this application in view of the above amendments and the following remarks.

1. Status of the Claims

Claims 1-26, 28-34 and 36-52 were pending in this application. In the present amendments, Claims 22, 33, 46, 48 and 49 have been canceled. Accordingly, Claims 1-21, 23-26, 28-32, 34, 36-45, 47 and 50-52 are currently pending for examination on the merits.

2. Summary of the Amendments

Claims 22, 33, 46, 48 and 49 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of these claims in a subsequently filed related application.

Claim 47 has been amended to insert the phrase "a therapeutically effective amount of" before "a compound of claim 1 or 2." Support for this amendment is found, for example, on page 100, lines 08-09.

Entry of these amendments is respectfully requested.

3. Rejections Under 35 U.S.C. §112, Second Paragraph

Claim 47 has been rejected under 37 U.S.C. §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner has indicated that Claim 47 is indefinite because it does not recite any dosage.

In response, Applicants have amended Claim 47 as kindly suggested by the Examiner to insert the phrase "a therapeutically effective amount." Accordingly, this rejection may be withdrawn.

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4. Rejections Under 35 U.S.C. §112, First Paragraph

A. Enablement Rejections

Claims 48-49 have been rejected under 37 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants have canceled Claims 48 and 49 and therefore, this rejection may be withdrawn.

B. Written Description Rejections

Claims 1-23, 26, 28-34, 36-50 and 51 have been rejected under 37 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. For the following reasons, this rejection is respectfully traversed.

For a written description rejection, the Examiner bears the burden of establishing a *prima facie* case to support the rejection. See, for example, *Ex parte Sorenson*, 3 USPQ 1462, 1463 (B.P.A.I 1987) (citing *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (C.C.P.A. 1976)) (“the examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in [the] specification disclosure a description of the invention defined by the claims.”).

In the present case, the Examiner’s sole basis for the rejection is the statement “[t]he mix and match of combinations of variables lacks antecedent basis, description and enabling support from the specification.” (Page 8, first full paragraph of Office Action). This unsubstantiated conclusion, which is not supported by any evidence or reasons, is not sufficient to establish a *prima facie* case of lack of written description. Accordingly, in the absence of further evidence or reasons, this rejection is improper and must be withdrawn.

Since the Examiner has not established a *prima facie* case of lack of written description, Applicants are not required to rebut the Examiner’s conclusions. However, Applicants wish to note on the record that the Examiner’s conclusions are, in fact, incorrect. Applicants have not “mixed and matched” combinations of variables that are not described in the application as originally filed. Specifically, each variable described in the rejected claims was present in the claims as originally filed – no new claims have been added which mix and match variables. Additionally, each claim is fully supported by a corresponding written description in the

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application. In this regard, the Examiner's attention is directed, for example, to page 26, line 17, where the statement "[a] preferred value for A is phenyl or pyridine" corresponds to Claim 3 which recites "[t]he compound of claim 1 or 2 wherein A is phenyl or pyridyl"; and page 26, line 18 where the statement "[a] preferred value for R¹ is hydrogen, methyl, or ethyl" corresponds to Claim 4 which recites "[t]he compound of claim 1 or 2 wherein R¹ is hydrogen, methyl, or ethyl"; and so on for each of the pending claims. Additionally, the specification provides methods of synthesis (see, e.g., page 83, line 17 to page 85, line 03; page 94, line 08 to page 97, line 27; page 102, line 05 to page 103, line 05) and an extensive lists of starting materials (see, e.g., tables on pages 31 to 75 and pages 85 to 94) for preparing compounds of the invention, including over one-hundred specific examples of such compounds (see, e.g., Tables A and B on pages 103 to 109).

Since the Examiner has not established a *prima facie* case of lack of written description, Applicants respectfully request that the rejection of Claims 1-23, 26, 28-34, 36-50 and 51 under 37 U.S.C. §112, first paragraph, be withdrawn.

5. Objections to the Claims

The Examiner has indicated that Claim 46 allegedly lacks antecedent basis because it recites the limitation "as described in Table A and Table B." Applicants also wish to bring to the Examiner's attention that Claims 22 and 33 make reference to "Table 1."

Claims 22, 33 and 46 have been canceled. Accordingly, this objection may be withdrawn.

6. Obviousness-Type Double Patenting

Claims 24-26 and 51 have been rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1 and 3 of U.S. Patent No. 6,693,202. In response, Applicants are submitting herewith a terminal disclaimer in compliance with 37 C.F.R. §1.321(c). Accordingly, this rejection may be withdrawn.

Applicants note that the filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Quad*

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Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). Specifically, the courts have indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection."

7. Information Disclosure Statement

Applicants wish to bring to the Examiner's attention that a Supplemental Information Disclosure Statement (IDS) was mailed for this application on August 22, 2002. This IDS was entered into the PAIR System on August 29, 2002. To date, Applicants have not yet received an Examiner-initialed copy of the Form 1449 which accompanied this IDS. Applicants respectfully request that the Examiner consider the information provided in this IDS and send an initialed copy of the Form 1449 to Applicants with the next Office Action. Should the Examiner require a duplicate copy of this IDS, the Examiner may contact the undersign attorney for Applicants.

IV. CONCLUSIONS

Reconsideration of this application in view of the above amendments and remarks is respectfully requested. Applicants believe this application is now in condition for allowance and a notice to that effect is respectfully requested. Should there be any issues that can be resolved by telephone or any questions concerning this response, the Examiner is requested to telephone the undersigned attorney at (650) 808-6406.

Respectfully submitted,
THERAVANCE, INC.

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